TCT-91

Six-Year Outcomes Following Endovascular Therapy with Nitinol Stenting for TransAtlantic Inter-Society Consensus C-D Lesions in the Femoro-popliteal Segment

Tomoharu Dohi[1], Osamu Iida[1], Yoshimitsu Soga[2], Kenji Suzuki[3], Keisuke Hirano[4], Shinsuke Nanto[5], Masaaki Uematsu[1]
[1]Kansai Rosai Hospital, Amagasaki, Japan; [2]Kokura Memorial Hospital, Kitakyushu, Japan; [3]Sendai Kosei Hospital, Sendai, Japan; [4]Saiseikai Yokohamashi Tobu Hospital, Yokohama, Japan; [5]Osaka University, Suita, Japan

Background: TransAtlantic Inter-Society Consensus (TASC) guideline recommended femoro-popliteal (FP) bypass as standard treatment for TASC C-D lesions. Although several studies have identified 5-year primary patency for FP bypass of around 70%, complication rate is high compared with endovascular therapy (EVT). Accordingly, EVT with nitinol stent implantation has been widely used for FP lesion. However, long-term results of stenting, especially for TASC C-D lesions, remain unclear. Thus, this study examined long-term outcomes of nitinol stent implantation for TASC C-D FP lesions, factors associated with the restenosis and risk stratification according to predictors.
Methods: Between December 2003 and December 2009, 381 patients with 471 TASC C-D FP lesions (mean age 72.4 years; 67.5% male) underwent nitinol stent implantation. Restenosis was defined either by duplex ultrasound or angiography. Patency was analyzed by Kaplan-Meier estimation. Predictors for restenosis were determined by Cox multivariate regression analysis, and primary patency rates were compared between low or high risk groups that were created based on number of predictors present.
Results: Mean lesion length was 230±65mm. At 6 years, the primary and secondary patency rate and amputation-free survival rate was 51%, 77% and 72.7%, respectively. By Cox multivariate regression analysis, female gender (hazard ratio [HR] 1.51; 95% confidence interval [CI] 1.09-2.10; P=0.014), diabetes (HR 1.73; 95% CI 1.15-2.59; P<0.01), claudicator (HR 1.73; 95% CI 1.15-2.59; P<0.01), without SMART stent implantaion (HR 1.66; 95% CI 1.17-2.35; P<0.01), and reference vessel diameter < 6mm (HR 1.49; 95% CI 1.07-2.99; P=0.017) were the predictors for restenosis. Primary patency in the low-risk group (number of risk factors 0-2) and high-risk group (3-5) at 6 years was 60.0% vs. 35.4%, p<0.0001, respectively.
Conclusion: EVT using nitinol stents yielded acceptable outcomes out to 6 years in TASC C-D FP lesions. Revascularization strategy for TASC C-D lesions should be chosen according to risk stratification.

TCT-92

WITHDRAWN

TCT-93

COMPLIANCE 360°: A Prospective, Randomized, Multicenter Trial Comparing Balloon Angioplasty to Diamondback 360° Orbital Atherectomy System in Calcified Femoropopliteal Disease

Raymond Dattilo
St. Francis Health Center, Topeka, KS

Background: Stent placement in the distal superficial femoral and popliteal arteries is associated with increased risk of stent fracture and restenosis. Lesion calcification is predictive of vessel dissection and recoil after PTA. This study examines whether the Diamondback 360° Orbital Atherectomy System (DB360) (Cardiovascular Systems, Inc., St. Paul, MN), by changing the compliance of calcified femoropopliteal (FP) lesions through the mechanism of differential sanding, diminishes the frequency of adjunctive (bailout) stenting without sacrificing intermediate term patency.
Methods: 50 symptomatic patients (66 lesions) from 10 sites with calcified FP lesions of ≥70% were equally randomized to PTA alone vs. DB360 followed by low pressure PTA up to 4 atmospheres (atm) with the endpoint of residual stenosis ≤30%. Lesions failing to achieve this endpoint with the prescribed therapy were then treated with bailout stenting. Freedom from target lesion revascularization (TLR), including the need for bailout stenting, or restenosis defined as a peak systolic velocity ratio of ≥2.5 on duplex study at 6 months, was the primary endpoint.
Results: 92.1% of 38 lesions in the DB360 arm and 21.4% of 28 lesions in the PTA arm (p<0.0001) met the angiographic endpoint after primary therapy. 2 of 25 pts in the DB360 arm vs. 21 of 25 pts in the PTA arm required bailout stenting (p<0.0001). Mean maximum balloon pressure (a measure of lesion compliance) in the DB360 arm was 3.9 atm vs. 8.5 atm in the PTA arm (p<0.0001). At 6 months, 4 pts in the DB360 arm vs. 3 pts in the PTA arm had restenosis (p=NS); 2 of 3 in the PTA arm were in-stent. Freedom from TLR or restenosis at 6 months was 72.7% (16 of 22 pts) in the DB360 arm and 8.3% (2 of 24 pts) in the PTA arm (p<0.0001).
Conclusion: Compared to PTA alone, orbital atherectomy with low pressure PTA leads to better luminal gain by improving lesion compliance with less need for adjunctive stenting when treating calcified FP lesions. Patency at 6 months is comparable to PTA with a provisional stent strategy.

TCT-94

Results of the ALSTER hypertension registry: first experience with renal denervation

Martin W Bergmann, Astrid Kleinbongardt, Alessandro Cuneo, Jasper Wedel, Karl Heinz Kuck
Dep. of Cardiology, St. Georg Hospital, Hamburg, Germany

Background: Renal denervation was found to be effective in drug-resistant hypertension. Here we dscribe the results of the first 31 patients treated outside the study criteria regarding reduction of drug intake and effectiveness.
Methods: Between Mai 2010 and January 2011 31 patients were treated with the Ardian simplicity system. These patients were followed for 6 months with repetitive diabetes and hypertension monitoring. No side-effects related to the ablation were documented. Patients were required to have at least 3 medications on board to be eligible; systolic blood press was measured at least once > 160 mmHg. In addition, echo criteria regarding diastolic dysfunction, HbA1c as a measure of glycemia control as well as renal function were closely monitored.
Results: After a 6 months follow up, 65% of patients responded to the therapy with either a measurable drop in blood pressure measured at the oupatient follow up visit 3 months after the procedure (35%) and/or less dyspnoe on exertion. 16% of patients reduced their medication in part due to dizziness with the newly decreased blood pressure. No effect on HbA1c was detected in this cohort; HbA1 was > 5.9% in 55% of patients. No measurable effect on diastolic dysfunction was found during the above mentioned follow up period of 6 months.
Conclusion: Renal denervation was found safe and partially effectived; we have since altered our system. Re-evaluating the patients who did not respond to treatment suggest duration of hypertensive treatment to be an independent predictor.

TCT-95

Acute And Long-term Follow-up Results Of Renal Angioplasty In Takayasu Arteritis

Amar Narayan Patnaik, D. S Rao, B. Srinivas
Cardiology, Nizam's institute of medical sciences, Hyderabad, India

Background: Takayasu arteritis frequently presents with hypertension in young adults. Stenosis of one or both renal arteries is present in most of them and angioplasty of these lesions is expected to control hypertension and control renal damage. We present the acute and long term results of renal angioplasty done for the last 8 years in our hospital.
Methods: All cases of Takayasu arteritis, diagnosed basing on criteria suggested by Ishikawa, who underwent percutaneous transluminal renal angioplasty (PTRA) in our hospital from 2003 were followed up clinically and by a renal Doppler in all cases at all visits. A cine renal- angiogram was advised at 6 months and 18 month visit. During 2003 to 2008, we performed renal angioplasty in 85 lesions (76 patients; 54 females; age range 24 to 47 years; mean 29.5±5.65 years). Unilateral lesions were seen in 67 patients and rest had one lesion in each kidney. Ostial lesions constituted % (29/85) of the cases. Of them 64 cases who had at least 18 months follow-up data were included for analysis.
Results: Results: Technical success rate for the first PTRA was 90.5%)(77/85) lesions. Of the 8 failure cases one with bilateral lesions was sent for emergency surgery due to renal artery rupture following PTRA and 5 underwent surgical revascularization. Of the ostial lesions technical success rate was 68.9 % (21/29). There was no mortality in any case. On a mean follow up of 22.5±8.55 months 19 of 64 cases {23 of 66 lesions (34.8%)} developed restenosis and 17 of them were successfully redilated. There was death of one patient with bilateral lesions due to CRF. Cure of hypertension (BP <140/90 mmHg without need for medication) and improvement (BP<140/90 mmHg with same or reduced number of medications) was achieved in 25/64(39%) and 24/64(37.5%) respectively. Of the 25 cases with raised serum creatinine 17/25 (68%) had shown a fall in their values in follow-up (mean 1.91± 1.05mg to 1.3±0.76 mg; p-<0.005)
Conclusion: PTRA is technically feasible with acceptable acute results. Ostial lesions are more difficult to be dilated. The restenosis is seen in about one-third of the cases after successful procedure which can be redilated. Control of hypertension and renal dysfunction is achieved in a significant number of cases.

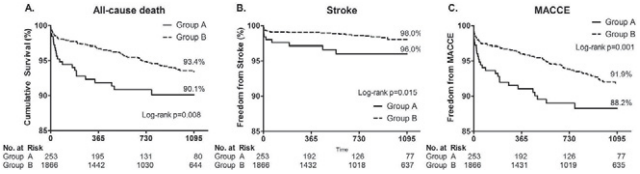
TCT-96

Impact of Preexisting Cerebral Ischemia Detected by Magnetic Resonance Imaging and Angiography on Clinical Outcomes After Coronary Artery Bypass Graft in Patients Without History of Stroke

Won-Jang Kim, Sun-Joo Jang, Yong Kyu Park, Gyung-Min Park, Yong-Giun Kim, Jung-Min Ahn, Jong-Young Lee, Duk-Woo Park, Soo-Jin Kang, Seung-Whan Lee, Young-Hak Kim, Cheol Whan Lee, Seong-Wook Park, Seung-Jung Park
Asan Medical Center, Seoul, Republic of Korea

Background: Limited data existed for long-term clinical outcomes of asymptomatic brain ischemia after coronary artery bypass grafting (CABG). We sought to assess the impact of preexisting ischemia detected by brain magnetic resonance imaging and angiography (MRA) on clinical outcomes after CABG.
Methods: Between Jan. 2003 and May 2009, 3,071 patients underwent CABG in Asan Medical Center. Preoperative brain MRA was performed in 2,417 patients. Patients

with history of stroke were excluded and total 2,119 patients were analyzed. Ischemia was detected by brain MRA in 253 patients (group A), but not in 1866 patients (group B). Preoperative characteristics, follow-up survival, and cardiac and neurological events were investigated.
Results: The median follow-up period was 2.2 years. Univariate analysis showed that patients in group A (65.4 ± 8.3 years) were older than those in group B (63.0 ± 9.0 years) (p<0.001). Diabetes mellitus was more common in group A (48.6%) than group B (40.9%) (p=0.019). The prevalence of chronic kidney disease was higher in group A (63 patients: 24.9%) compared with group B (324 patients: 17.4%) (p=0.004). The prevalence of peripheral vascular disease was higher in group A (13 patients: 5.1%) than in group B (39 patients: 2.1%) (p = 0.003). Euroscore was higher in group A (4.3 ±2.3) than group B (3.6 ±2.2) (p<0.001). Survival rate was significantly lower (93.4% vs. 90.1%, p = 0.008), and freedom from stroke or major adverse cardiac and cerebrovascular event were significantly lower in group A (98.0% vs. 96.0%, p = 0.015, and 91.9% vs. 88.2%, p = 0.001).



Conclusion: Preexisting ischemic findings on brain MRA in patients who undergoing CABG were related to death, stroke, and major adverse cardiac and cerebrovascular event.

TCT-97

From US Pivotal Study to 1200 Patients on 6 Continents: A Global Perspective on the Endurant Stent Graft

Brijeshwar Maini
PinnacleHealth Cardiovascular Institute, Wormleysburg, PA

Background: Endovascular abdominal aortic aneurysm (AAA) has evolved since first being approved in the US in 1999. Outcomes have changed with increased operator experience and the approval of new devices. The Endurant stent graft system (Medtronic, Santa Rosa CA) which was approved in late 2010 is the first next generation device to be commercialized in the US. This device seeks to expand the indications of EVAR in short, angulated necks, as well as, patients with small peripheral access vessels. However, are US pivotal study results indicative of global experience?
Methods: Over 1400 patients have been enrolled in Endurant clinical studies or registries since first in human studies commenced in Europe. The three studies used in this analysis are the Endurant European study which enrolled 80 patients, the US Pivotal study which enrolled 150 patients, and the ENGAGE global registry. Data from the ENGAGE registry includes results from the first 839 patients at 30 days and the first 152 patients at 1 year.
Results: Deployment success was achieved in 99.6% of patients across all studies. In the US Pivotal study there was 0% all-cause mortality at 30 days. In comparison, 30 day all-cause mortality in the EU study and ENGAGE were 2.5% and 0.9% respectively. At 1 year, there were no incidences of Type I/III endoleak, migration, or conversion in either the US Pivotal or the EU study. Similarly, there was a 1% incidence of Type I/III endoleak, no incidence of migration, and a 0.8% incidence of conversion at 1 year in ENGAGE.
Conclusion: Early and midterm outcomes with the Endurant stent graft system in the treatment of AAA are consistent across global studies with high clinical success and low complication rates.

TCT-98

Carotid Artery Revascularization with Distal Protection in High Surgical Risk Patients in Routine Clinical Practice: Results of the CABANA Safety Surveillance Program

L. Nelson Hopkins[1], Christopher J White[2], Malcolm T Foster[3], Richard J Powell[4], Gerald Zemel[5], Juan Diaz-Cartelle[6], Keith D Dawkins[6]
[1]University at Buffalo, State University of New York, Buffalo, NY; [2]John Ochsner Heart and Vascular Institute, Ochsner Clinic Foundation, New Orleans, LA; [3]Mercy Medical Center West, Knoxville, TN; [4]Dartmouth Hitchcock Medical Center, Lebanon, NH; [5]Good Samaritan Medical Center, West Palm Beach, FL; [6]Boston Scientific Corporation, Natick, MA

Background: The multicenter, nonrandomized CABANA Study evaluated periprocedural outcomes in high surgical risk patients with carotid artery stenosis treated with the Carotid WALLSTENT plus FilterWire EZ Embolic Protection System (Boston Scientific Corporation, Natick, MA).
Methods: The study enrolled 32.7% symptomatic and 67.3% asymptomatic patients at high risk for carotid endarterectomy (CEA) due to prespecified anatomical criteria and/or medical comorbidities. Study centers were grouped into 1 of 3 tiers based on having high, medium, or low previous carotid artery stenting (CAS) experience while individual operators were grouped by their CAS credential-based study training requirements. Follow-up at 30 days included clinical evaluation and independent neurologic and NIH stroke scale assessments. The primary endpoint was the 30-day composite of major adverse events (MAE), including stroke, death, and myocardial infarction (MI).
Results: Of the 1,097 enrolled patients, technical success was achieved in 1,010 (97.1%); the stroke rate (3.3% [34/1,025]) was a major contributing factor in the overall rate of MAEs (4.6% [47/1,025]). Most strokes were ipsilateral (88.2%) and ischemic (85.3%). The overall mortality was 1.3% (13/1,025); the MI rate was 0.5% (5/1,025). There was no statistically significant association between MAE rates among the 3 center experience tiers (p=0.61) nor among the 3 operator training categories (p=0.26). However, there was a weak trend towards lower MAE rates at centers with greater experience and with operators with more CAS training.
Conclusion: Results demonstrate that CAS with Carotid WALLSTENT and FilterWire EZ is a safe alternative to CEA in high surgical risk patients in routine clinical practice. The study yielded a low composite rate of 30-day MAEs and low individual rates of periprocedural stroke, death, and MI. These rates were consistent across centers with varying levels of CAS experience and operators with varying levels of training on CAS and the Carotid WALLSTENT/FilterWire EZ System.

TCT-99

The SAPPHIRE Worldwide Carotid Artery Stenting with Embolic Protection Study: Outcomes to 1-Year with Over 7,600 Patients

Christopher Metzger[1], Robert Hibbard[2], Douglas Massop[3], Richard Smalling[4], Donald Heck[5], Maurice Solis[6]
[1]Holston Valley Medical Center, Kingsport, TN; [2]Bryan Heart Institute, Lincoln, NE; [3]Iowa Clinic, Des Moines, IA; [4]University of Texas Medical School, Houston, TX; [5]Forsyth Memorial Hospital, Winston-Salem, NC; [6]Medical Center of Central Georgia, Macon, GA

Background: Carotid artery stenting (CAS) has become a viable alternative to carotid endarterectomy, especially in patients considered high risk for surgery due to medical co-morbidities and anatomically challenging lesions. SAPPHIRE Worldwide is the largest study to date to evaluate long-term outcomes of CAS in patients at high-risk for surgery.
Methods: SAPPHIRE Worldwide is a multicenter, prospective, observational study of CAS performed at multiple centers by physicians with varied experience and utilizing a formal training program. The primary endpoint of major adverse events (MAE) included death, myocardial infarction (MI) and all stroke at 30 days, and ipsilateral stroke was assessed from 31 to 360 days.
Results: To date, over 10,000 patients have been enrolled at 325 participating centers and completed 30-day follow-up. More than 7,600 patients have completed 1-year follow-up evaluation. Thirty percent of patients enrolled were symptomatic, and 46% were over the age of 75 years. At 30-day follow up, the rate of MAE was 4.5% (death 1.3%, MI 0.6%, all stroke 3.3%). Between 30 days and 1 year, 21 additional patients suffered an ipsilateral stroke for a 1-year MAE rate of 6.1%. MAE was significantly lower in patients with asymptomatic vs. symptomatic stenosis (5.1% vs. 8.6%, p<0.0001), and in patients with anatomic high risk factors compared with physiologic factors (4.2% vs.6.9%, p<0.0001). Age < 75 years was also associated with a lower risk of adverse events than seen with older patients (4.5% vs. 8.1%, p<0.0001).
Conclusion: Long-term outcomes with this large cohort of patients undergoing CAS, shows favorable results. The risk of ipsilateral stroke after the periprocedural period was very low at 0.3%.

Imaging

Room 120

Tuesday, November 8, 2011, 10:15 am - 12:25 pm

(Abstract nos 100 - 109)

ORALS

TCT-100

Neoatherosclerosis and Late Stent Thrombosis After Coronary Bare-Metal Stent Implantation: an Optical Coherence Tomography Study

Yuetsu Kikuta, Hideo Takebayashi, Shigeki Hiramatsu, Kenji Goto, Masahito Taniguchi, Sunao Kodama, Katsumasa Sato, Yasukazu Fujiwara, Arata Hagikura, Seiichi Haruta
Fukuyama Cardiovascular Hospital, Fukuyama, Japan

Background: Little is available on the neointimal characteristics of the lesions with late stent thrombosis (ST) after bare-metal stenting.
Methods: We evaluated 53 consecutive nonostial stent failure lesions in 53 patients (8 ST and 45 restenoses) by optical coherence tomography.
Results: At the index procedure, 29 patients (55%) were treated for acute coronary syndromes. The median duration of implant was 58.8 months (interquartile range, 8.8 to 117.7 months). Three ST patients (6%) presented with ST-segment elevation myocardial infarction (STEMI), 1 (2%) with non-STEMI, and 4 (8%) with unstable angina. Stent malapposition was detected in 12 lesions (23%). The risk of ST (n = 8) versus restenosis (n = 45) was increased for the patients with low LVEF (mean ± SEM, 47.2 ± 3.2% versus 55.6 ± 1.6%, p = 0.04), high LDL/HDL cholesterol ratio (2.7 ± 0.2